SIBELMED W-50

AUDIOMETRY SOFTWARE

USER MANUAL

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Sibelmed®

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CONTENTS

DECLARATION OF CONFORMITY 5

1. INSTRUCTIONS FOR USE AND INSTALLATION 7

INTRODUCTION 8

INTRODUCTORY INFORMATION 8

MANUFACTURER'S RESPONSIBILITIES 9

INSTALLATION, SETTING UP AND REQUIREMENTS 9
INSTALLING THE AUDIOMETRY SOFTWARE 9
USB INSTALLATION DRIVER 11
SETTING UP 12
ACTIVATION CODE 13
ACQUIRING THE PROGRAM 14
UNINSTALLING THE AUDIOMETRY SOFTWARE 15
COMPUTER SETUP AND REQUIREMENTS 16
PRINTER SETUP AND REQUIREMENTS 17

2. W-50 AUDIOMETRY SOFTWARE 19

INTRODUCTION 20

ABOUT THE ON-SCREEN HELP 21

MAIN MENU 22

CONFIGURATION MENU 23
SELECT PRINTER 24
LINKS 25
OTHER 26
REPORT HEADER 26
PARAMETERS AND OTHER 26
FINISH 27

OPTIONS MENU 29
DATABASE 29
EXPLORE DATABASE 30
PATIENT FILE 39

Contents

DATABASE MAINTENANCE 41
AUDIOMETRY 47
IMPORT TESTS 60

HELP MENU 61
ABOUT THE HELP SYSTEM.....61
ABOUT THE SOFTWARE 61
MAIN MENU 61
GO TO THE SIBEL SITE.....61

3. AUDIOMETRY 63

INTRODUCTION 64

TYPES OF AUDIOMETRY 67
PURE TONE THRESHOLD AUDIOMETRY 64
PURE TONE SUPRATHRESHOLD AUDIOMETRY.....65
SPEECH AUDIOMETRY OR LOGOAUDIOMETRY 66

APPLICATIONS OF AUDIOMETRY 67

DIAGNOSES 68

4. TECHNICAL SPECIFICATIONS 69

SOFTWARE COMPATIBILITY AND COMPUTER REQUIREMENTS 70

PARAMETERS 71

PERSONALISING THE PROGRAM 71

DATABASE 71

STANDARDS 72

5. MAINTENANCE 73

6. MODIFICATIONS..... 75

APPENDIX1. COMPLIANCE WITH ORGANIC LAW ON DATA PROTECTION 77

APPENDIX 2. DIAGNOSIS 85

DECLARATION OF CONFORMITY

The **SIBELMED W-50 Audiometry Software** has been developed for use with **SIBELMED** brand audiometers by **SIBEL S.A.**'s **R, D & I** department in accordance with the Sibel S.A. Quality Manual and therefore in accordance with the **ISO 13485** quality standard, as well as the **European Medical Device Directive 93/42/EEC**. Under this directive, it is regarded as a class IIa product.

CE 0318

PRODUCT CONFORMS WITH
93/42/EEC Medical Devices Directive
Class II a

Revised
Date: 2012-05

José Maria Plana
Technical Director

Approved
Date: 2012-05

Carlos Recio
Sales Director

Declaration of Conformity

1. INSTRUCTIONS FOR USE AND INSTALLATION

INTRODUCTION

SIBELMED W-50 is software for viewing, storage, transfer, analysis and entry of audiometric tests for use under the Microsoft Windows environment.

SIBELMED W-50 Audiometry Software has been developed for use with **SIBELMED** brand audiometers by **SIBEL S.A.**'s **R, D & I** department in accordance with the Sibel S.A. Quality Manual and therefore in accordance with the **ISO 13485** quality standard, as well as the **European Medical Device Directive 93/42/EEC**. Under this directive, it is regarded as a class IIa product.

INTRODUCTORY INFORMATION

This product is manufactured under strict quality control. However, accidents can occur during the transport or storage of the equipment. It is therefore advisable to carry out an initial check on its condition, and that of the accompanying accessories, before installation.

The **SIBELMED W-50 Audiometry Software** comprises:

CODE	QUANT.	DESCRIPTION
520-660-001	1	**SIBELMED W-50 Audiometry Software**
520-690-001	1	W-50 Communication software
520-660-MU1	1	Instruction manual

MANUFACTURER'S RESPONSIBILITIES

SIBEL S.A. guarantees the safety, reliability and proper functioning of this equipment provided that:

- The computer in which the software is installed complies with the IEC (UNE) electrical installation requirements for medical products, and such other standards as may apply.

- Repairs, maintenance and modifications, whether within the warranty period or otherwise, are carried out by SIBEL S.A. technical staff.

- The software is used by qualified staff following the recommendations for use, in accordance with the Instruction Manual.

INSTALLATION, SETTING UP AND REQUIREMENTS

INSTALLING THE AUDIOMETRY SOFTWARE

WARNING:
If installing the software under the Windows NT 4, Windows 2000, Windows XP or Windows Vista operating systems, the user must have Administrator privileges for the program to install correctly. In case of doubt consult the system Administrator or Windows Help.

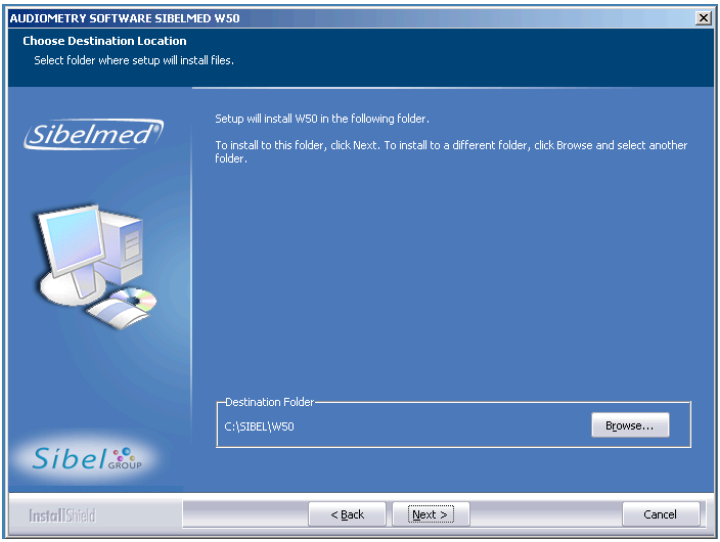
To install the Software on the hard disk of the PC proceed as follows:

1 Place the **CD_ROM** in the CD/DVD drive.

2 If the CD/DVD drive has autoplay enabled, installation will start automatically. If not, run the file **Setup.exe** on the software CD.

3 When setup starts, the following window appears offering the choice of install language.

4 Choose the folder where the program is to be installed and the program group name. By default the program is installed in the folder **:\SIBEL\W50**.


AUDIOMETRY SOFTWARE SIBELMED W50
Choose Destination Location
Select folder where setup will install files.
Sibelmed
Setup will install W50 in the following folder.
To install to this folder, click Next. To install to a different folder, click Browse and select another folder.
Destination Folder
C:\SIBEL\W50
Browse...
Sibel GROUP
InstallShield
< Back
Next >
Cancel

5 Once the installation is finalised the **SIBEL** program group is created and a short-cut is added to the desktop.

USB INSTALLATION DRIVER

A driver needs to be installed on the computer in order to USB communications between **SIBELSOUND 400** and **SIBELMED W-50** software work properly.

To install the Driver, follow these steps:

1 Start up the audiometer (consult the corresponding user manual).

2 Insert the W-50 Installation CD into the computer.

Windows **98**, **2000**, **XP** and **Vista**:

3 Connect the audiometer to the computer with the USB cable (consult the corresponding user manual). As it is the first time that the equipment is connected to the computer, the Windows «New Hardware Detected» screen will appear, with the name of the equipment that you have connected. Select «Next».

4 A screen will appear that allows you to select between two options:

First: Find best controller for your device.

Second: Show a list of all controllers in a location.

Select the Second and click on Next.

5 Now a screen will appear which allows you to select between Show All Hardware or Show Compatible Hardware. Select «Show all Hardware» and click the «Use Disk» button.

6 If your operating system is Windows 98, select the file D13Test in the directory D:\Driver\W98 of the audiometry CD. For others

operating systems (Windows 2000, Windows XP), select the file Sibelusb of the directory D:\Driver\W2K_WXP_WVISTAx32. Press OK.

7 Click on Next and Finish. The Driver will now install itself.

Windows Vista:

3 Connect the audiometer to the computer with the USB cable (consult the corresponding user manual). As it is the first time that the equipment is connected to the computer, the Windows «New Hardware Detected» screen will appear, with the name of the equipment that you have connected. Select «Next»

4 A screen where you will be able to read «Insert the disc came with your **device name**» will appear, select «I don't have the disc. Show me other options».

5 Now a screen will appear that allows you to select between two options, select «Browse my computer for driver software».

6 If your operating system is a Windows Vista 32 bits version, select the directory D:\Driver\ W2K_WXP_WVISTAx32 of the audiometry CD. For Windows Vista 64 bits, select the directory D:\Driver\WVistax64. Press OK.

7 Click on Next and Finish. The Driver will now install itself.

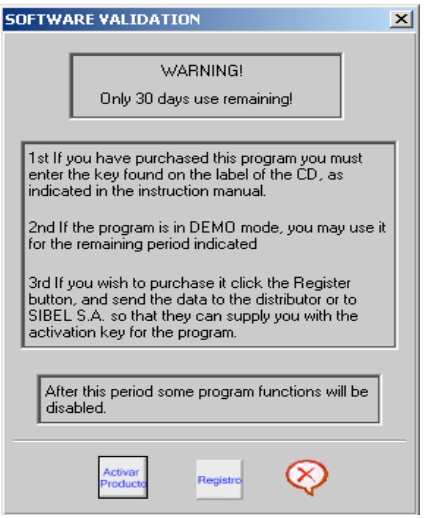
START-UP

Reboot the PC and launch the program by clicking on the **W-50** icon under **All Programs > SIBEL** from the Start menu, or double-clicking on the **W50** short-cut on the desktop.

Press **OK** on the **ABOUT...** screen to access the MAIN WINDOW.

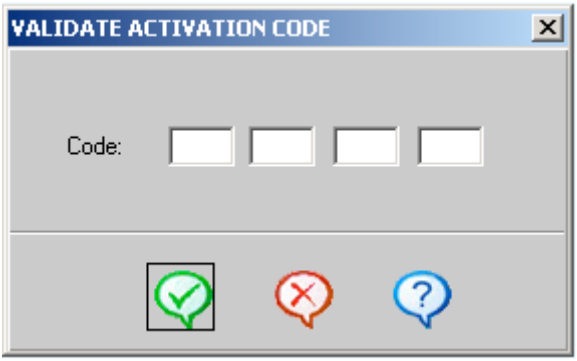
ACTIVATION CODE

This option is to activate the program once when it's used with SibelSound 400 audiometer the trial period has expired (program in DEMO mode).
During this period of 30 days, the program notifies the number of days remaining before the end of the above-mentioned period by means of the following dialog box:


SOFTWARE VALIDATION
WARNING!
Only 30 days use remaining!
1st If you have purchased this program you must enter the key found on the label of the CD, as indicated in the instruction manual.
2nd If the program is in DEMO mode, you may use it for the remaining period indicated
3rd If you wish to purchase it click the Register button, and send the data to the distributor or to SIBEL S.A. so that they can supply you with the activation key for the program.
After this period some program functions will be disabled.
Activar Producto
Registro

This screen allows ti activate the software by means of the activation code if the Activar Producto options selected. It also allows to ask for the activation code if the Registro Options selected. When the specified evaluation period is finished, some software functions are desactivated. The following warning message is shown:

To activate the program, you must connect the SIBELSOUND 400 audiometer by means of the USB or RS232 wire. Following, select the options Utilities/Activation Code from the Configuration menu o select the Activar Producto option from the SOFTWARE VALIDATION dialog box the following dialog box is shown.



Enter the activation code provided when the software was purchased.
From then onwards you are free to use the Sibelmed W50 Software without restriction.

ACQUIRING THE PROGRAM

This option allows you to enter the required data to get the activation code and send them bay e-mail to SIBEL,S.A. or to your distributor.

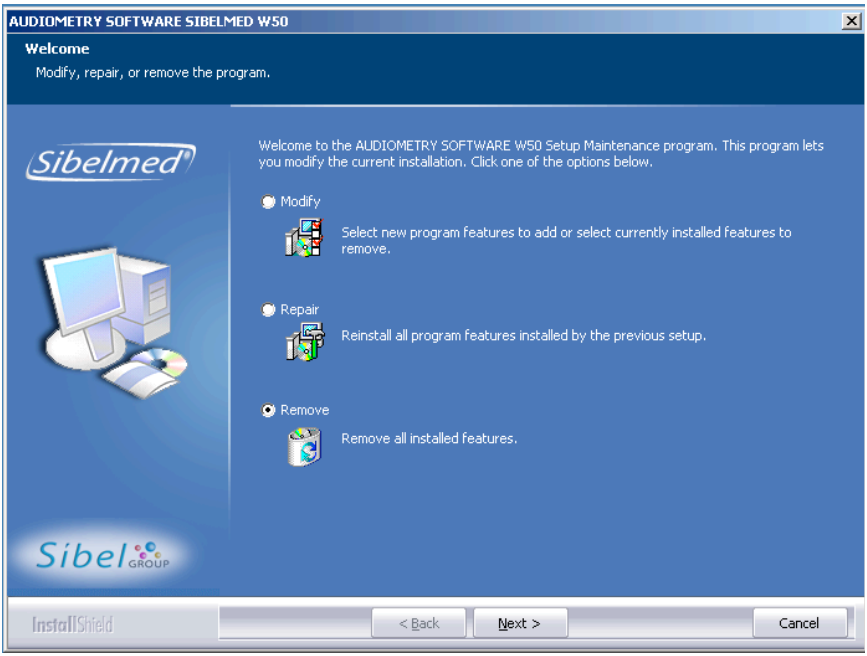
You can acquire the software with theRegistro option from the SOFTWARE VALIDATION dialeg box or the Utilities/Purchasing the Program option from the setup menu.

UNINSTALLING THE AUDIOMETRY SOFTWARE

1 Place the **CD_ROM** in the CD/DVD drive.

2 If the CD/DVD drive has autoplay enabled, installation will start automatically. If not, run the file **Setup.exe** on the software CD.

3 The following window appears, from which you can choose one of the following options:


AUDIOMETRY SOFTWARE SIBELMED W50
Welcome
Modify, repair, or remove the program.
Sibelmed
Welcome to the AUDIOMETRY SOFTWARE W50 Setup Maintenance program. This program lets you modify the current installation. Click one of the options below.
Modify
Select new program features to add or select currently installed features to remove.
Repair
Reinstall all program features installed by the previous setup.
Remove
Remove all installed features.
Sibel GROUP
InstallShield
< Back
Next >
Cancel

- **Modify**: Allows uninstallation by modules. This option is not recommended as you might lose the database if a backup copy has not been made. Use the option ***Remove*** to carry out the uninstall.

- **Repair**: Reinstalls the program.

- **Remove**: Completely removes the software, but retains the database in the folder in which the program was installed.

COMPUTER SETUP AND REQUIREMENTS

The setup of the computer must be carried out in accordance with its Instruction Manual.

The computer used must comply with the **minimum requirements** set out below:

	Minimum	**Recommended**
Hard disk:	1 Gb	20 Gb or larger
Graphics card:	800 x 600	800 x 600 or better
Monitor:	15”	17”

Operating system: Windows 98, 2000, XP or Vista.

Backup unit: Recommended

It is advisable to select **large fonts** under the operating system big letter fonts size option for easier viewing of the program. This option can be found under display properties. See the manual for the computer's operating system.

PRINTER SET UP AND REQUIREMENTS

The setup of the printer should be carried out in accordance with its Instruction Manual.

The printer used should comply with the **minimum requirements** set out below:

- Windows compatible printer
- 160 PPP resolution
- 5 pages per minute.
- Compliance with standards applicable to printers.

2. AUDIOMETRY SOFTWARE W-50

INTRODUCTION

The **SIBELMED W-50 Audiometry Software** operates under the Microsoft Windows environment and provides as its main features:

Management of various patient databases

Download of data from audiometric tests carried out with the AC50 or SIBELSOUND 400 audiometers

Manual entry of data from audiometric tests carried out with other audiometers

Viewing of the individual audiometric tests

Obtaining diagnoses

Printing of test reports

ABOUT THE ON-SCREEN HELP

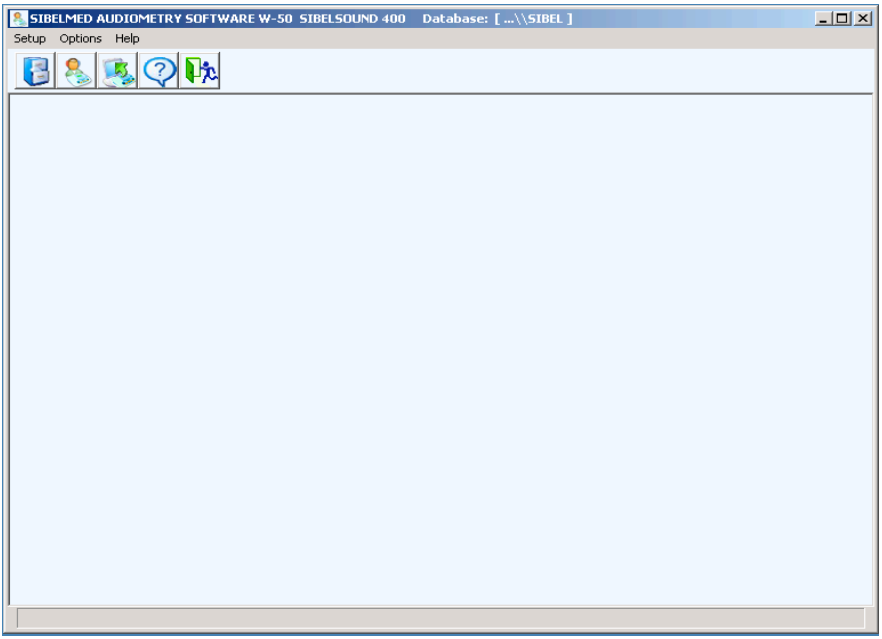
The help incorporated into the **SIBELMED W-50 Audiometric Software** is structured based on the MICROSOFT Windows system and shows the user how to make appropriate use of the program's various options. The Instruction Manual provides, in some cases, a more detailed explanation concerning technical specifications or other aspects.

In general, each window contains a Help menu where you can find an explanation of the various options available. The help feature is marked on each window with an icon, text or both.

In some sections of text you will find words or phrases which link to further help for a more detailed explanation. To do this, place the cursor above the underlined word, the cursor changing to a hand; clicking the left mouse button causes the relevant help to be displayed.

MAIN MENU

This window shows the main options available from the **SIBELMED W-50 Audiometry Software** with the corresponding sub-options:



SETUP

- Select Printer
- Links
- Other
- Utilities (only when the SIBELSOUND 400 audiometer is selected in the setup/Links menu).
- Exit

OPTIONS MENU

- Database
- Audiometry
- Import tests

HELP MENU

- About Help
- About the Software
- Main menu
- Go to the SIBEL website

Using each of these options provides access to the relevant information.
There are also five icons for rapid access to some of the menus which correspond to: Explore database, Audiometry, Load data, Help and Finish.

A description of each of the functions which can be carried out by the **SIBELMED W-50** software is set out below.

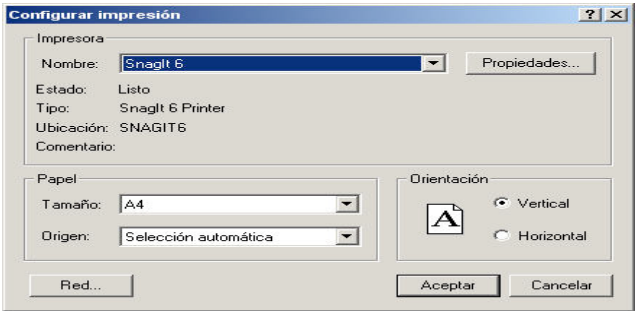
SETUP MENU

The **SIBELMED W-50 Audiometry Software** is a versatile program supporting a variety of functional options. Some of these may not be relevant to some users. Therefore, once the process of Installation and Activation has been completed, it needs to be customised to the needs of each user. Accordingly, the system becomes personalised to each user making it simpler to operate and to understand how it works.

The various options that can be personalised from the configuration menu are set out below.

SELECT PRINTER

This option is for configuring a page for printing (size, origin, orientation) and indicates the printer selected by the operating system, as well as the available printers.
If the required printer is not listed, it must be added in the normal way for the operating system. Refer to the Manual for the Operating System.



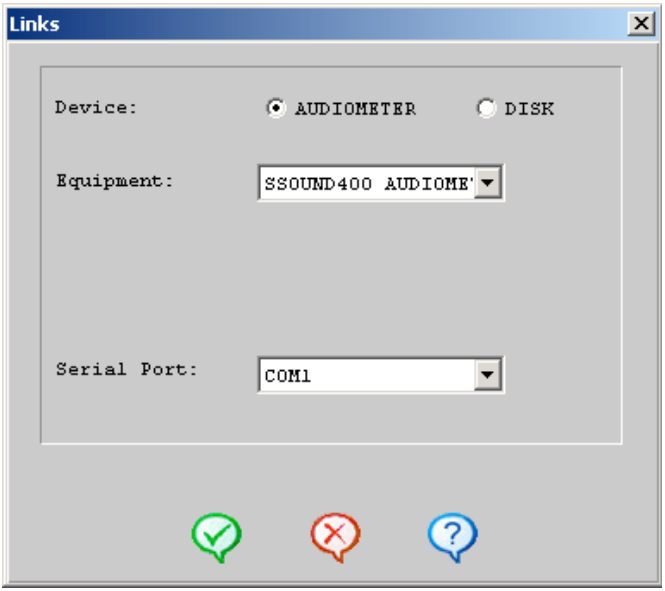
LINKS

From this window you can select:

- The equipment (AC50, SIBELSOUND 400 or manual entry)

- The device (Audiometer or Disk). The "Disk" option includes some standard recorded tests so that the software can be tried out without the need to carry out a test.

- The serial port for communication between the equipment and computer. If USB comunications are used (only SIBELSOUND 400), this parameter doesn't take any effect.

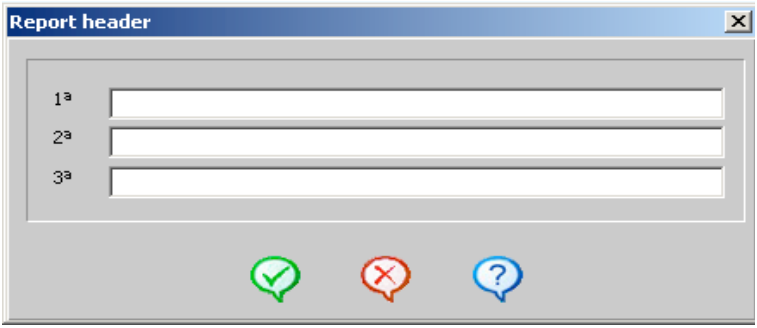


OTHER

From this menu option you have access to:

REPORT HEADER

A three line header can be inserted in printed reports with data chosen by the user. For example: Name of centre, name of doctor, address, etc.



This header remains in force until modified.

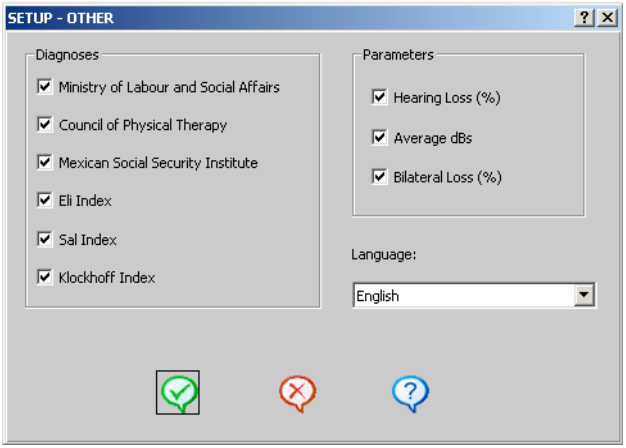
PARAMETERS AND OTHER

This window is for selection of:

- The type of diagnosis for the pure tone audiometry test Ministry of Labour ans Social Affairs(Council of Physical Therapy, Mexican Social Security Institute, Eli Index, Sal Index and Klockhoff Index).

- The parameters which we wish to view in the pure tone audiometry test.

- The language for the application.



EXIT

To finisch the program and return to Windows use the exit option.

UTILITIES

This option is only available if the SIBELSOUND 400 audiometer and the device Audiometer are selected in the Setup / Links menu. The following options are shown:

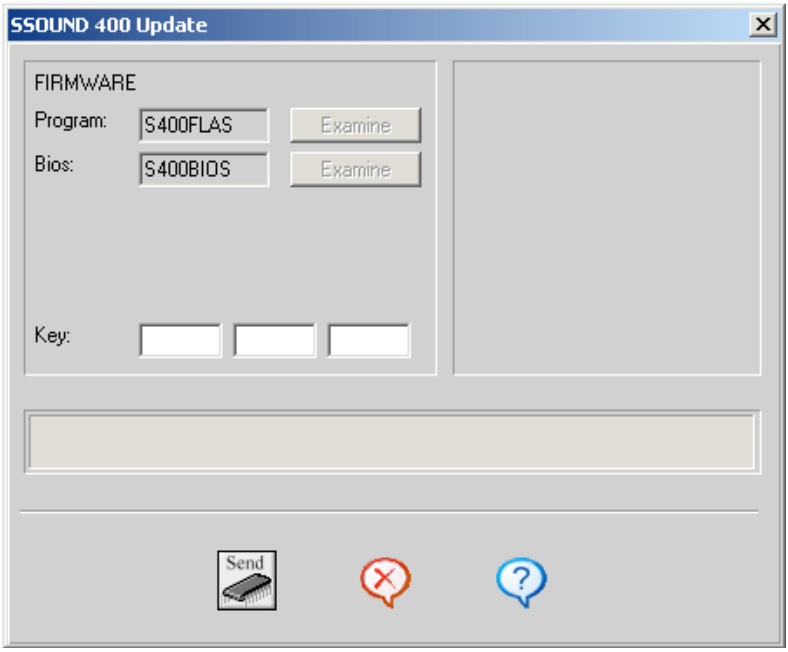
- Update Flash
- Purchasing the program (see the topic ACQUIRING THE PROGRAM)

Activating the program (see the topic ACTIVATION CODE)

UPDATE FLASH

The **SIBELSOUND 400** audiometer of **SIBEL S.A.** has a firmware updating and maintenance process.

Before starting the update process, check that the device is ON and connected to the computer. If you are using serial communications, check if the selected port in Setup / Links menu is correct. To update the version of the firmware, the Setup / Utilities / Update Flash option must be selected. From the SSOUND 400 Update dialog box, enter the key supplied with the audiometer, click the SEND button and verify the evolution of the loading process in the screen.



WARNING
DON'T CANCEL THE LOAD PROCESS WHEN IT HAS STARTED.

Finally a «transmission correct» message will appear. So the new firmware runs smoothly, you must leave the loading screen, turn off the audiometer and turn it on again. From now on, the device will work perfectly with the new firmware version.

If there was an error during the load process, it's possible to restart the firmware update. You must leave the loading screen, turn off the device and turn it on again. A screen with the following text will be shown in the audiometer: ACT. FIRMWARE / UPDATE FIRMWARE. From this moment, the firmware update process must be repeated.

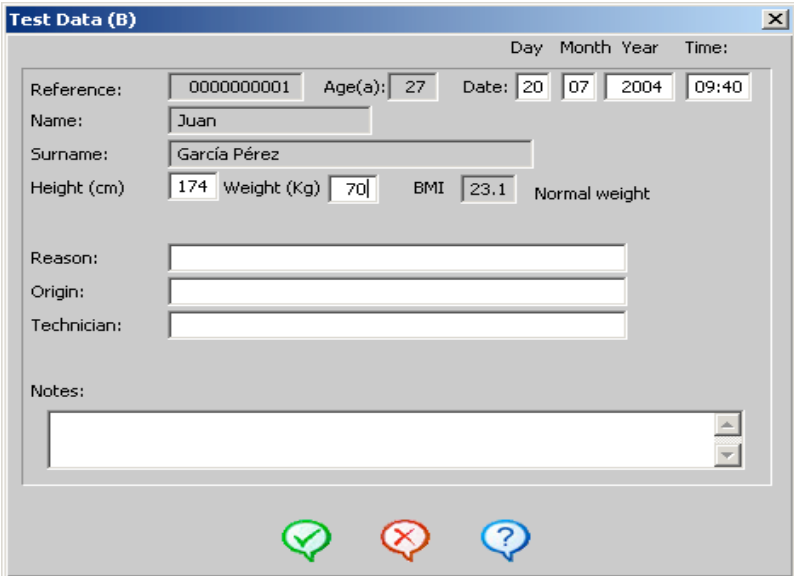
OPTIONS MENU

DATABASE

The **SIBELMED W-50 Audiometry Software** can be used with various databases in accordance with the user's needs. This option provides access to the data structures set up when configuring the system and is therefore for storage and management of information generated when carrying out audiometric tests.

For this purpose the following sub-options are provided:

EXPLORE DATABASE



From this window you can see the relationships between the patients in the database and their respective tests, and in turn have access to the following options from the **menu**:

- Setup
- Database
- Options
- Window
- Help

There are **icons** provided for rapid access to: Load Tests (Load), Export tests in CSV format (EXP), Import tests in CSV format (IMP), Test data, Print Report, Print Preview, Help and Exit (RET).

- **SETUP**

See the Topic MAIN MENU / SETUP MENU

- **DATABASE**

PATIENT CARD

See the Topic MAIN MENU / OPTIONS MENU / DATABASE / PATIENT CARD

TEST CARD

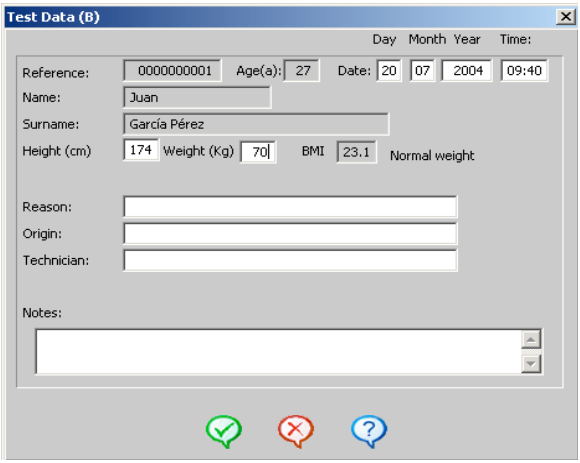
The test card shows the following data concerning the patient (on a read-only basis):

Reference
Age in **years**
Name
Surname
BMI (Body Mass Index)

And other items may be entered such as:

Date and **time** the test was carried out
Height in **cm** between 100 and 215 cm
Weight in **Kg.** between 15 and 135 Kg.

Reason for carrying out the test
Origin or centre, department, doctor, etc. from where patient was referred
Technician who carried out the test
Notes on the test



DATABASE MAINTENANCE
See the Topic MAIN MENU / OPTIONS MENU / DATABASE / MAINTENANCE

• OPTIONS

IMPORT TESTS

See the Topic MAIN MENU / OPTIONS MENU / IMPORTS TESTS / IMPORT TESTS

EXPORT TESTS IN CSV FORMAT

Allows tests to be exported in CSV format.
To do this you must:

1 Mark the tests you wish to export.

2 Click on the **EXP** icon or select the option **Export tests in**

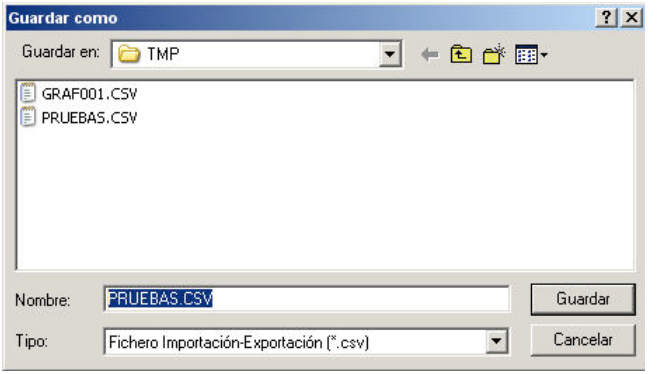
CSV format from the Options menu.
The "Save As" window then appears.

3 Enter the name of the **file** and the **folder** to which you wish the data to be saved.

4 a Click the **Save** button to save the data. At this point the file is created.

or

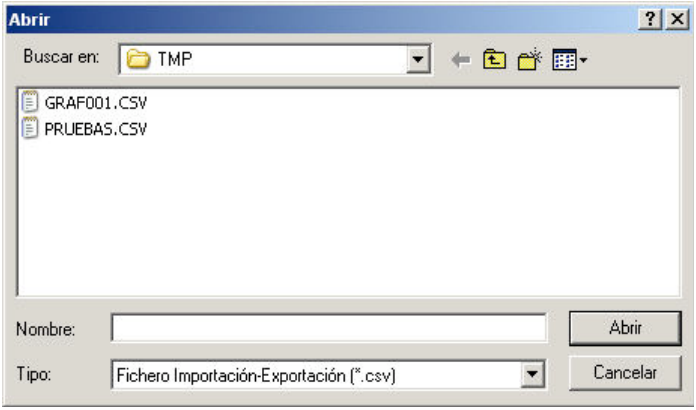
b Click the **Cancel** button to return to the previous window without saving the data.



IMPORTING TESTS IN CSV FORMAT

Allows tests saved in CSV format to be imported.
To do this you must:

1 Click the **IMP** icon or select the **Import tests in CSV format** from the Options menu.
The "Open" window then appears.

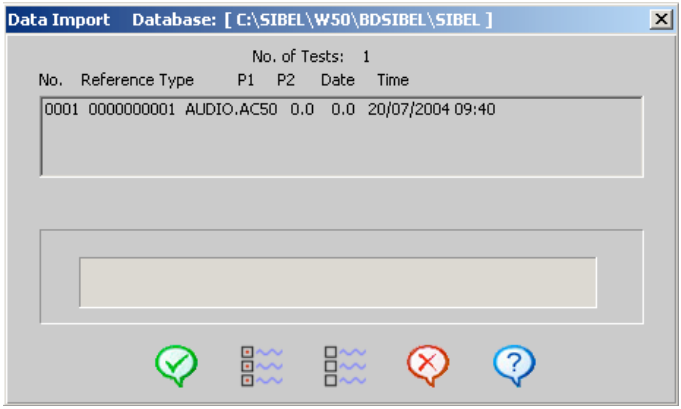


2 Find the **folder** containing the file to import and select the **file**.

3 a Click the **Cancel** button to return to the previous screen without importing data.

or

b Click the **Open** button to proceed with the data import. The "Data Import" window appears showing the tests contained in the selected file.


Data Import Database: [C:\SIBEL\W50\BDSIBEL\SIBEL]
No. of Tests: 1
No. Reference Type P1 P2 Date Time
0001 0000000001 AUDIO.AC50 0.0 0.0 20/07/2004 09:40

4 **Select** the required tests by clicking on the relevant test, or select all of them using the Select All button (to unselect click on the relevant test or click the Unselect All button).

5 Click the **OK** button to import the selected tests. The bar at the foot of the window indicates that the import process is in progress. At the end of the process it indicates that the data import is complete.
At this point the tests have been saved in the database.

EXPORT TESTS BY EMAIL

Allows tests to be sent by email.
To do this you must:

1 Mark the tests you wish to email.

2 Select the **Export tests by email** option from the Options menu.
The email system installed in the PC then opens, displaying a new draft message with an attachment called TESTS containing the data for the selected tests.

3 Enter the destination email address and any message text.

4 Click Send to send the email.

TEST DATA

Opens the tests window to view graphs, parameters, diagnoses, etc. relating to the selected test.

PRINT REPORT

Prints a report of the selected test.

PRINT PREVIEW

Opens a window showing a preview of the report so you can check it is the report you want and is correctly formatted before printing.

The following options are available:
Report: prints the report.
Forward/Back: moves forwards/backwards within the report so that all pages can be previewed.
Zoom Out/In: allows to decrease/increase the dimensions of preview of the last.
Help: displays Help in relation to the print preview function.
Return: returns to the previous window.

• WINDOW

SELECT

For selection of a patient or test. Where the
Patients window is active, on selecting a patient all that patient's tests are also selected.

UNSELECT

Unselects the selected patient or tests. Where the Patients window is active, on unselecting a patient all that patient's tests are also unselected.

SELECT ALL

Where the Patients window is active, all patients are selected together with all the tests.
If the Tests window for a patient is active, all the tests for the selected patient are selected.

UNSELECT ALL

Where the Patients window is active, all patients are unselected together with all the tests.
If the Tests window for a patient is active, all the tests for the selected patient are unselected.

CASCADE

Superimposes all the Patients and corresponding Tests subwindows in a cascade arrangement.

TILE HORIZONTAL

Arranges all the Patients and corresponding Tests subwindows above and below each other.

TILE VERTICAL

Arranges all the Patients and corresponding Tests subwindows side by side.

REFRESH

Refreshes the information in the windows.

SORT BY

Sorts the list of patients by criterion selected (record number, Surname or reference).

SHOW DELETED RECORDS

Shows those records marked for deletion.

- **HELP**

See the Topic MAIN MENU / HELP MENU

On clicking the **right button** of the mouse above a **patient** a menu appears with the following options:

DATA: provides access to the patient file.

DELETE: deletes the patient together with the corresponding tests.

UNDELETE: removes the deletion marker from a patient who has been marked for deletion.

Double-clicking on a **patient** opens their file.

On clicking the **right button** of the mouse above a **test** a menu appears with the following options:

DATA: accesses the test's data card.

DELETE: deletes the test.

UNDELETE: removes the deletion marker from a test which has been marked for deletion.

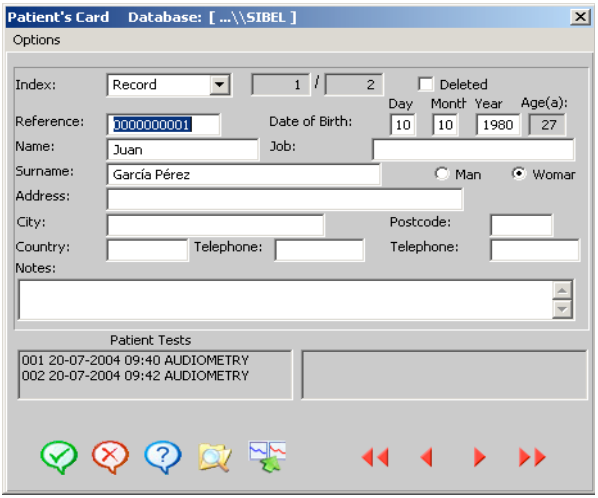
GRAPH: opens the test window.

REPORT: prints the relevant test.

Double-clicking on a **test** opens the test window.

PATIENT CARD

This window provides access to the **card** for any **patient** saved in the database and enables their various tests to be viewed along with their key parameters.



The fields associated with each card are:

NOTE: The patient data are fictitious.

Field	Type	No. characters
Index	A/N	
Reference	A/N	8
Date of Birth	N	8 (dd/mm/yyyy)
Name	A/N	20
Surnames	A/N	35
Job Sex	A/N	25
Address		
City	A/N	46
Postcode	A/N	28
Country	A/N	5
Telephone 1	A/N	10
	A/N	10
Telephone 2	A/N	10
Notes1	A/N	74
Notes2	A/N	74

A/N = Alphanumeric field
N = Numeric field

On clicking **Options** a drop-down appears with the following options:

REGISTER: Registers a new patient. A dialog box appears for entry of the new reference number. The program warns if the reference has already been used for another patient.

DELETE: Deletes a patient and all that patient's tests

UNDELETE: Undeletes the deleted records. To use this function you need to access the Options menu from the main window and

select Database - Maintenance and then activate the Show deleted records option.

FIND: Finds the file for the required patient. You can search by reference, surname or record number.

EXPORT: Opens the export window.

EXIT: Returns to the previous window.

The find and test data options are also available from the **icons** in the lower part of the window.

You can also use the **slow tab** keys (advance one record at a time) or the **fast tab** keys (move by 10 records at a time) to navigate through the database to find the required card.

The card shows the number of records in the database and the number of the selected record.

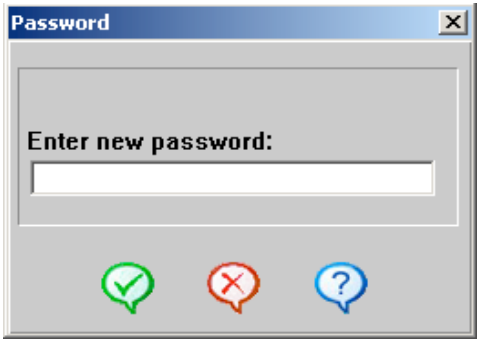
DATABASE MAINTENANCE

This Maintenance option refers only to the database on the computer, not the one in the audiometer. For information on the latter refer to the relevant Instruction Manual for the device**.**

The options provided are:

CHANGE PASSWORD

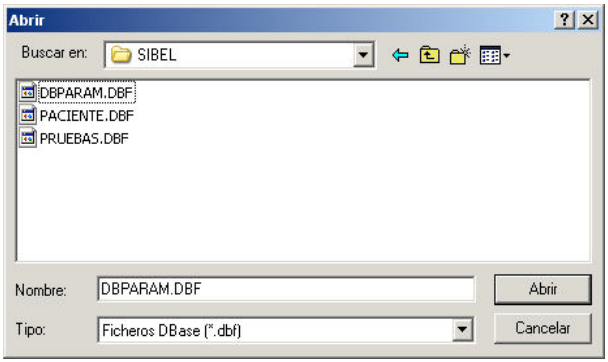
Changes the password for a database. The system requests the new password and confirmation of the latter.

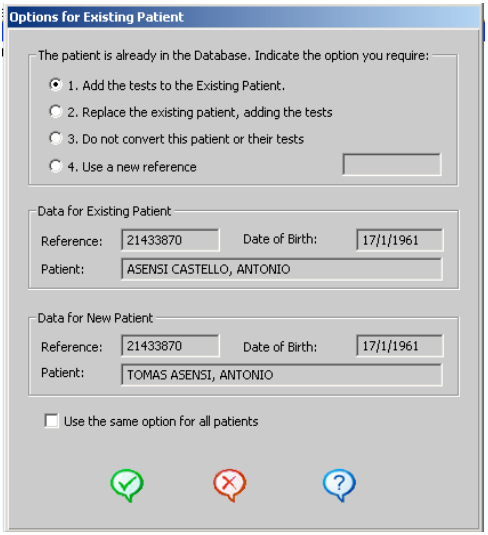


CONVERT DATABASE

Allows the format of old databases (created with the Audiometry Software under DOS) to be changed to the current format for SIBELMED W–50 Audiometry Software.

On using this option the following window appears:




Options for Existing Patient
The patient is already in the Database. Indicate the option you require:
1. Add the tests to the Existing Patient.
2. Replace the existing patient, adding the tests
3. Do not convert this patient or their tests
4. Use a new reference
Data for Existing Patient
Reference: 21433870
Date of Birth: 17/1/1961
Patient: ASENSI CASTELLO, ANTONIO
Data for New Patient
Reference: 21433870
Date of Birth: 17/1/1961
Patient: TOMAS ASENSI, ANTONIO
Use the same option for all patients

This shows the data for the new patient and the existing patient, and offers the choice of the following options:

1 Add the tests to the existing patient: The patient data is not changed; the only change is the addition of the new tests.

2 Replace the existing patient, adding the tests: The patient data is changed, but not the existing tests. The new tests are added.

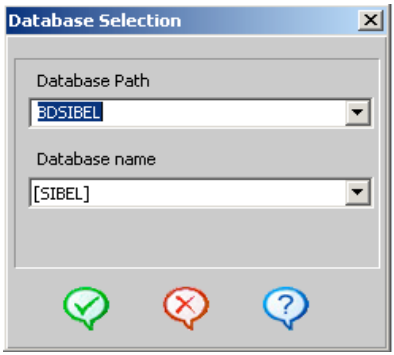
3 Make no change to this patient or their tests: the conversion is not carried out.

4 Use a new reference: a new reference is created for the new patient. In this event the new reference must be entered.

To apply the same choice for all patients use the tick-box located towards the lower part of the window.

SELECT DATABASE

Allows a database to be selected. To do this enter the **path** where it is located and select the database by **name**.



The path could be relative (e.g. BDSIBEL\BASE), or absolute (e.g. C:\BDSIBEL\BASE). Network drives can also be used, provided they are shared and have been given the necessary reading and writing permissions.

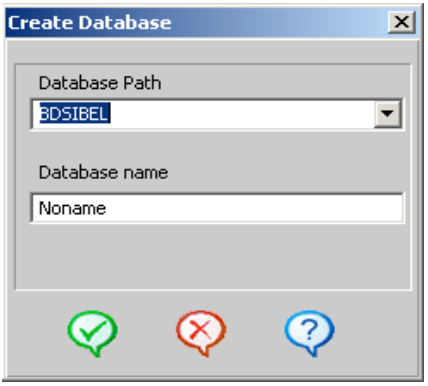
WARNING
If in any doubt consult the system administrator.

The path can be selected using the drop-down menu, or entered using the keyboard.
On selecting a path, the available Databases are listed, in the lower drop-down, DATABASE NAME.
On selecting a Database the following error message may be displayed: **"Not a Database"**. If this happens and the file selected does actually correspond to a Database, the latter must

be recreated with the same name and in the same location. This can be done by selecting the "Create Database" option from Options menu - Database - Database Maintenance. The existing data **WILL NOT BE LOST**.
On confirming the selected database, the PASSWORD is requested. Provide the same password as entered when the database was created.

CREATE DATABASE

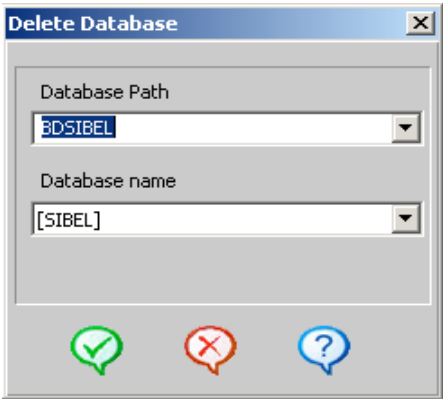
Creates a database. Enter the **path** and the **name of the database**. On confirming the name, a **password** is requested. The password must be entered a second time to confirm it.



DELETE DATABASE

On selecting the delete database option, the window lists the database or databases available and the user selects the one they wish to delete. On confirming the database to be deleted, the corresponding PASSWORD is requested. Provide the same password as entered when the database was created. **When a database is deleted** not only are the patient records eliminated but also corresponding graphs, parameters and **any other information recorded**.
It is very important to use a password which can be easily remembered.

If the password is forgotten, contact the SIBEL S.A. Aftersales Service who will explain the process to follow.



COMPACT DATABASE

This option is used to **permanently delete** records marked for deletion by the user and reorganise the remaining records in the database. This option can be used as often as the user wishes but may take some time to carry out, depending on the volume of data stored.

REINDEX RECORDS

Allows a database to be **reorganised** whenever any problem with it is encountered. This option can be used as often as the user wishes but may take some time to carry out, depending on the volume of data stored.

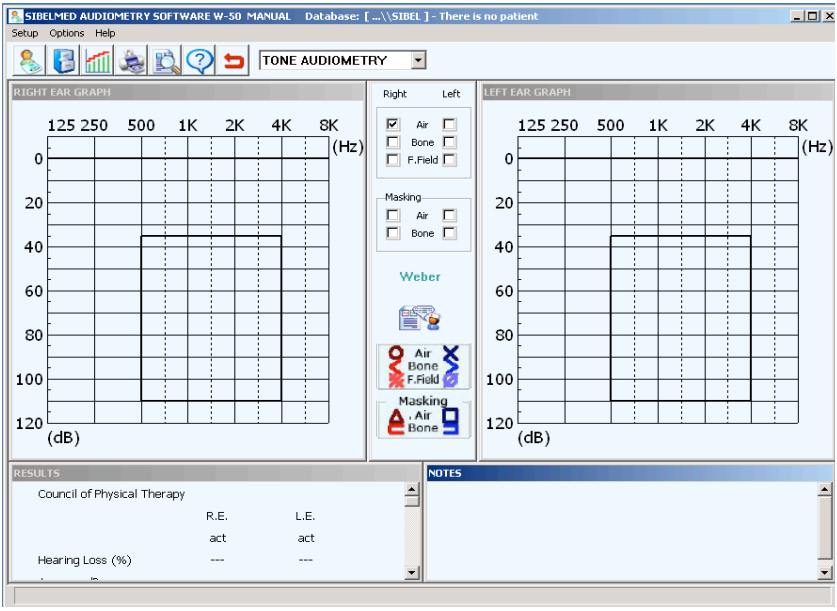
SHOW DELETED RECORDS

When a Database record is deleted, it remains hidden but is not

permanently deleted unless the compact database option is used. You can use this option at any time to see the records marked for deletion.

AUDIOMETRY

In this section we describe the various windows and functions which are specific to audiometry. The various audiometric tests and the procedure to carry them out are described in Chapter 3.



This window enables the user to **view** the results obtained on carrying out an audiometric test using the AC50 audiometer (select **AC50** in the Setup-Links window), SIBELSOUND 400 audiometer (select SSOUND 400 in the Setup/Links windows), or manually **enter** the data obtained on carrying out an audiometric test using another audiometer (select **MANUAL ENTRY** in the Setup-Links window).

The following options are available from the **menu**:

SETUP MENU

See the Topic MAIN MENU / SETUP MENU

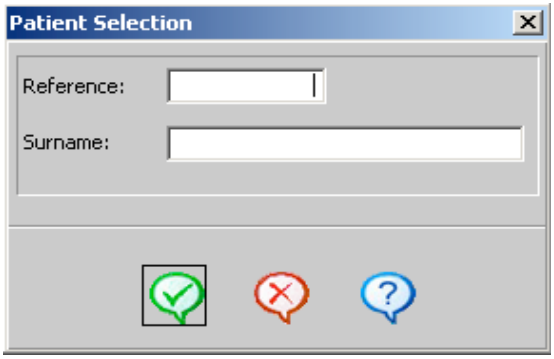
OPTIONS MENU

TESTS

Allows selection of the required audiometric test: Pure Tone Audiometry, Logoaudiometry, Sisi Jerger, Fowler, Tone Decay, Lüscher or Weber.

NEW PATIENT

Allows selection of a patient in the database or creation of a new one. To do this enter the patient reference.

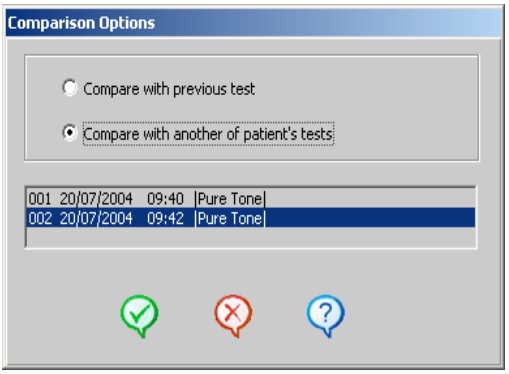


SAVE IN THE DATABASE

Saves the test in the database.

COMPARE

Selects a test against which to make a comparison: Previous test / Other test (in the latter case a window appears for selection of a test from the list of tests for the patient).
On selecting a test for comparison, it is displayed superimposed.


Comparison Options
Compare with previous test
Compare with another of patient's tests
001 20/07/2004 09:40 Pure Tone
002 20/07/2004 09:42 Pure Tone

PRINT REPORT

Prints a report based on the current test.

PRINT PREVIEW
See the Topic MAIN MENU / OPTIONS MENU / DATABASE / EXPLORE DATABASE

ORGANISE WINDOWS

This option allows the user to make proportionate changes to those windows which have been selected. The user can adjust the window sizes using the mouse and dragging any of the sides or vertices of a window.

HELP MENU

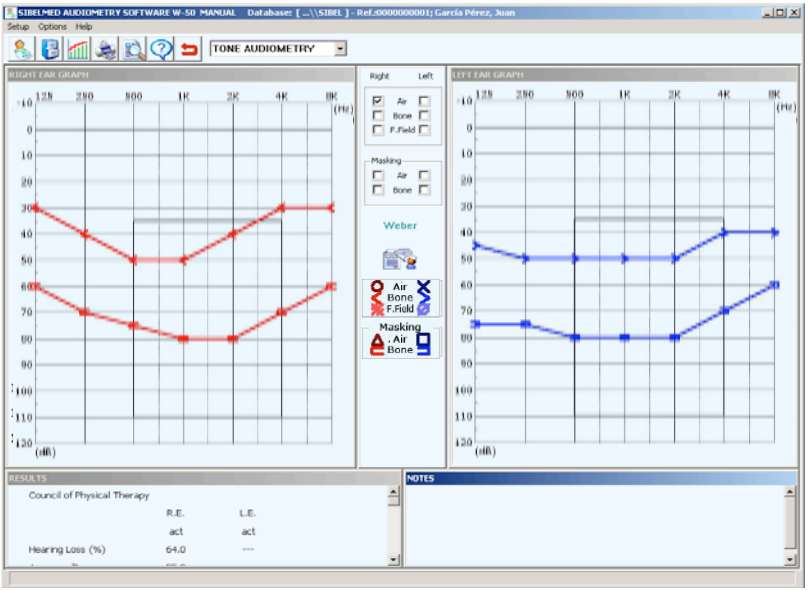
See the Topic MAIN MENU / HELP MENU

The following options are also available from the **icons** at the top of the window: New Patient, Save to database, Compare, Print Report, Print Preview, Help and Exit.

Test selection can also be carried out using the **drop-down menu** at the top of the window.

Depending on the selected test the following windows appear:

PURE TONE THRESHOLD AUDIOMETRY



- Window showing graph of Intensity v Frequency for the right ear

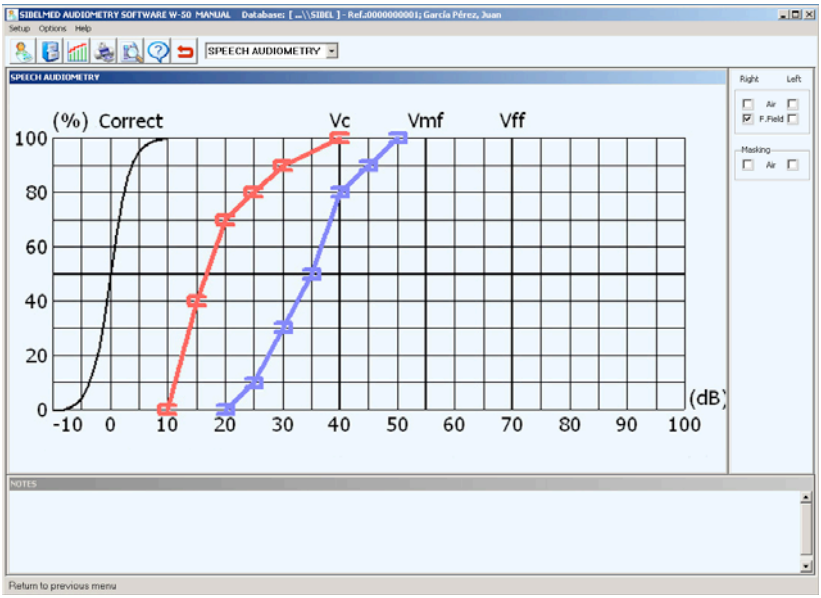
- Window showing graph of Intensity v Frequency for the left ear

- Central window for:
  - Selection of route (Air, Bone, Free)
  - Selection of masking
  - Weber Test
  - Access to diagnosis
  - Legend showing symbols for identification of conduction and masking

- Results window (Hearing loss, Average dB, Bilateral loss)

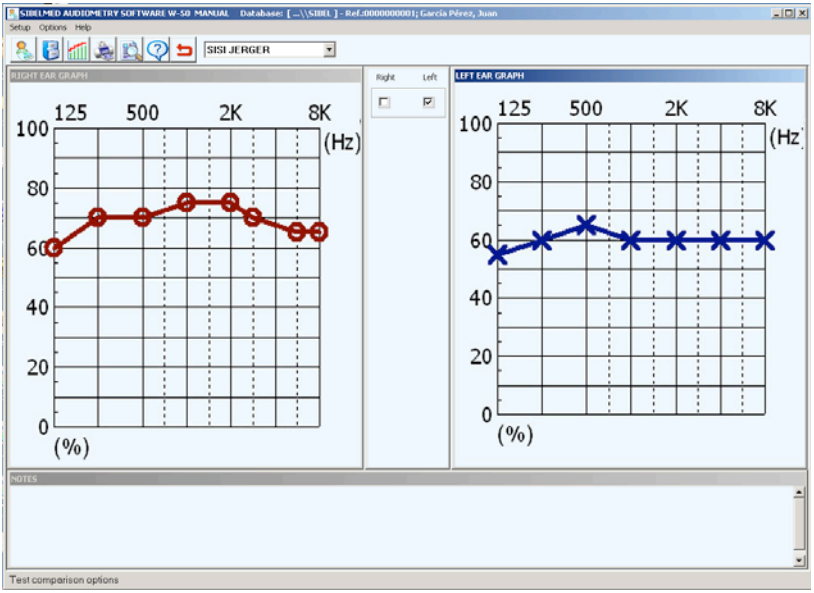
- Notes window

SPEECH AUDIOMETRY



- Window showing graph of Correct detections v Intensity
- Window for:
  - Selection of conduction (Air, Free)
  - Selection of masking
- Notes window

SISI JERGER TEST



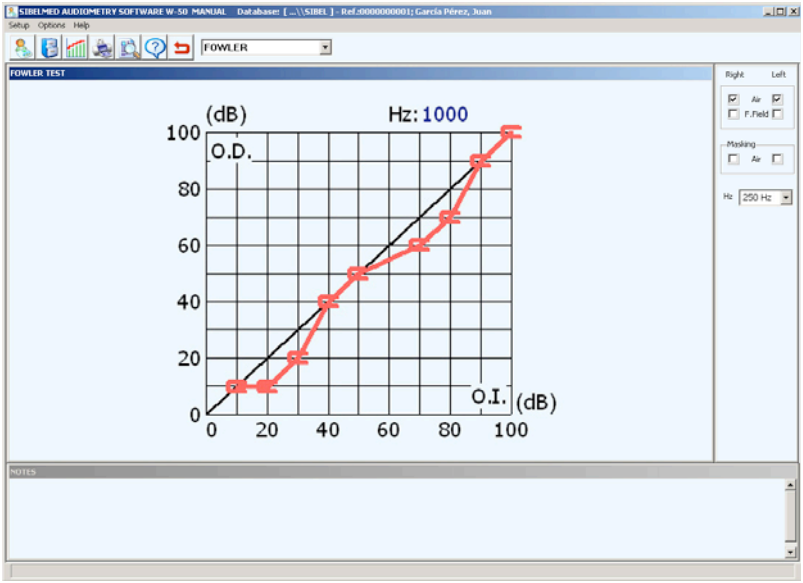
- Window showing graph of Correct Detections v Frequency for the right ear

- Window showing graph of Correct Detections v Frequency for the left ear

- Window for ear selection

- Notes window

FOWLER TEST

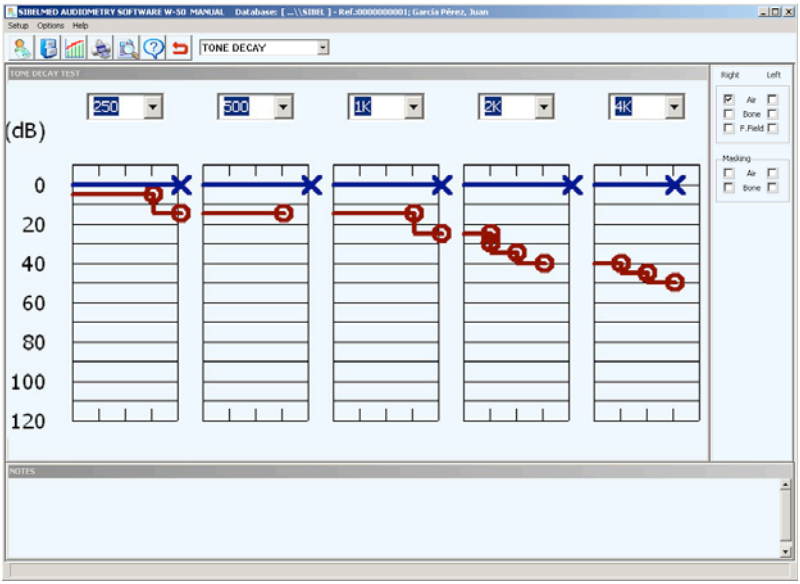


- Window showing graph of intensities

- Window for:
  - Selection of masking election of frequency (125 Hz to 8000 Hz)

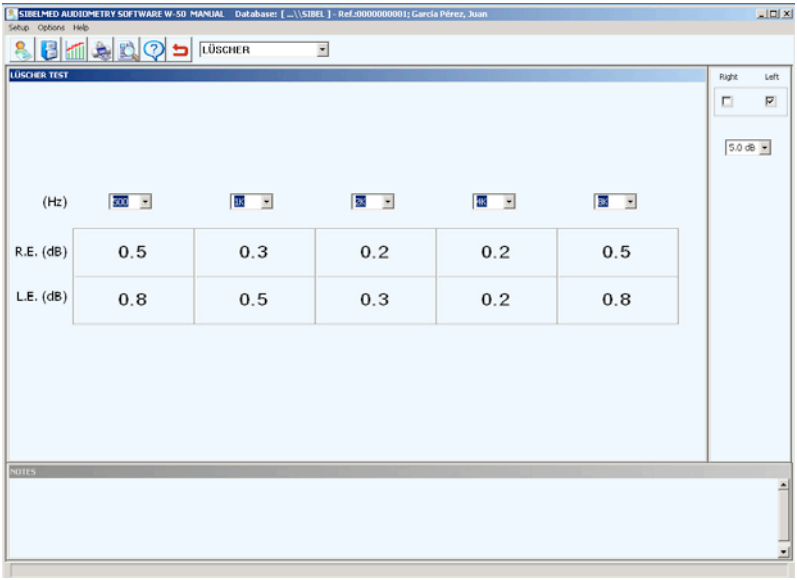
- Notes window

TONE DECAY TEST



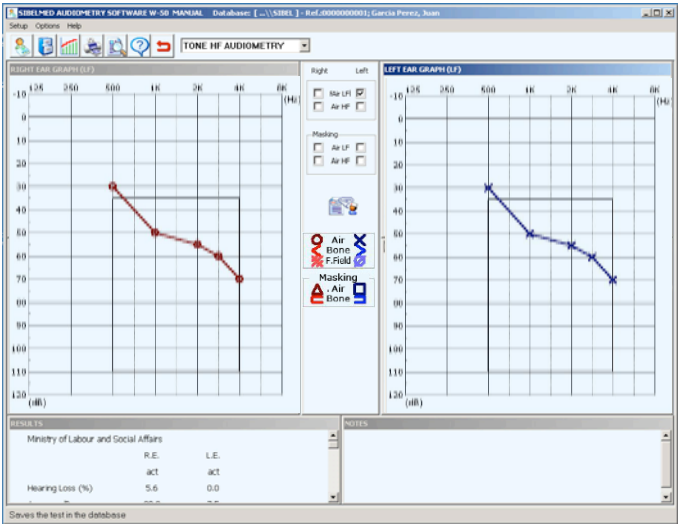
- Window showing graph of Intensity v Frequency
- Window for:
  - Selection of conduction (Air, Bone, Free)
- Notes window

LÜSCHER TEST



- Window showing table of intensities for each frequency
- Window for:
  - Selection of ear
  - Selection of intensities (0.2 dB to 5 dB)
- Notes window

PURE TONE HF AUDIOMETRY



- Window showing graph of Intensity v Frequency (LF) for the right ear
- Window showing graph of Intensity v Frequency (HF) for the right ear
- Window showing graph of Intensity v Frequency (LF) for the left ear
- Window showing graph of Intensity v Frequency (HF) for the left ear
- Central window with:
    - Selection of conduction (Air LF and Air HF)
    - Selection of masking
    - Access to diagnoses
    - Legend showing symbols for identification of conduction and masking
- Results window (Hearing loss, Average dB, Bilateral loss)
- Notes window

MANUAL ENTRY

Select this option from Setup + Links on the main window.
On accessing the tests window (Options + Audiometry) you can enter data manually from an audiometric test carried out with another audiometer.
To do this you must:

1 Select new patient (icon or Options menu + New patient)

2 Enter the latter's reference (can be new or an existing reference if the patient has already been registered in the database)

3 Enter the required data in the patient and test cards

4 Select the relevant test from the drop-down menu at the top of the window or from the Options menu + Tests.

5 Depending on the test, various options are available with regard to the application of signal and masking (see description of test windows above).
Select the required options.

6 Enter the data obtained, moving the cursor to the graph point corresponding to the result then clicking the left mouse button, and repeating for all data. These points are joined creating a graph of the test.

Once all the data has been entered you may:

- Enter notes by double-clicking on the notes window

- Save the test to the database (icon or Options menu + Save in the database)

- Print a report of the test (icon or Options menu + Print Report)
- Compare with other tests (icon or Options menu + Compare)
- Delete a point (right-click above the point).

IMPORTS TESTS

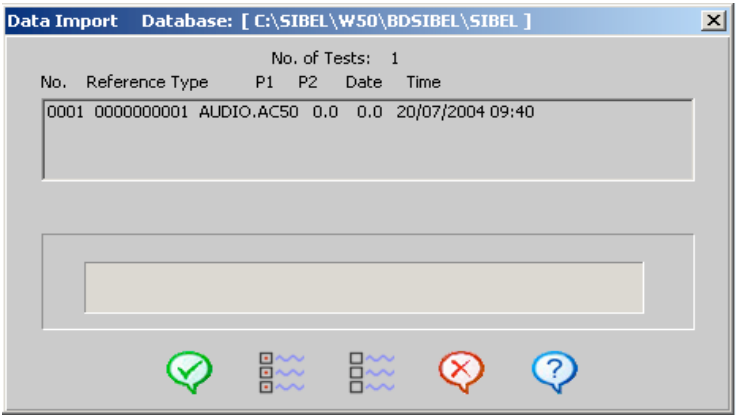
IMPORT TESTS

Loads test data stored in the audiometer.

Select the required tests by clicking on each one individually, or select all of them using the Select All button (to unselect a test click on it or click the Unselect All button).

Click the **OK** button to import the selected tests. The bar at the foot of the window indicates that the import process is in progress. At the end of the process it indicates that the data import is complete.
At this point the tests have been saved in the database.

Click **Cancel** to return to the previous window without loading data.


Data Import Database: [C:\SIBEL\W50\BDSIBEL\SIBEL]
No. of Tests: 1
No. Reference Type P1 P2 Date Time
0001 0000000001 AUDIO.AC50 0.0 0.0 20/07/2004 09:40

DELETE TESTS ON THE DEVICE

Deletes tests stored in the audiometer.

HELP MENU

ABOUT THE HELP SYSTEM

This window explains the Help system incorporated in the **SIBELMED W-50 Audiometry Software.**

ABOUT THE SOFTWARE

This window shows the **version of the program**, and also **information about SIBEL S.A.** for reference purposes.

MAIN MENU

This window offers access to an explanation of the various options in the main menu.

GO TO THE SIBEL WEBSITE

Accesses the SIBEL website on the Internet.

3. AUDIOMETRY

INTRODUCTION

The purpose of audiometry is to chart changes in hearing in response to acoustic stimuli.

The ear comprises two groups of anatomical structures:

- The Transmission System (middle and outer ear) which transmit vibrations to the inner ear.

- The Perception System which constitutes the sensory organ proper (inner ear with cochlea, nervous pathways and higher auditory centres).

TYPES OF AUDIOMETRY

There are three types of audiometry:

PURE TONE THRESHOLD AUDIOMETRY

This involves determining the minimum hearing thresholds for different frequencies by air conduction and bone conduction.

It is considered that the **hearing threshold** is the sound level at which, under specific conditions, a person achieves a response rate of 50% correct detections over a series of repeated trials.

Air conduction involves transmission of sound via the outer and middle ear to the inner ear.
Bone conduction involves transmission of sound to the inner ear principally via mechanical vibration of the cranial bones.

WEBER TEST

For this test all frequencies between 250 and 8000 Hz must be investigated, at 15 dB above the subject's frontal bone threshold. The vibrator is applied frontally, held in place with a headband not by hand, as the latter might allow variation pressure which could lead to error.
A note is made of which side the patient perceives the sound to be coming from.
This test is fundamental in clinical audiometry; its physiopathological significance is considered subsequently, for purposes of diagnosing deafness.

PURE TONE HF

It consists of realizing a pure tone audiometry in a range of frequencies extended up to 20.000 Hz. Unlike the classic pure tone audiometry, hearing thresholds are only inspected by air conduction.

PURE TONE SUPRATHRESHOLD AUDIOMETRY

These tests are for evaluation of distortions in the sensation of sound due to disorders in the perception System.

These tests include:

SISI JERGER TEST

This involves having the patient hear a continuous, pure sound at 20 dB above the threshold, for two minutes.
Every 5 seconds the intensity of the sound increases by 1 dB for 2/10 sec. The patient must signal the occurrence of this brief change in intensity, every time they perceive it.

- If they detect less than 20% of the instances, the test is negative.

- If they detect between 20% and 60% of the instances, the test is inconclusive.
- If they detect more than 60% of the instances, the test is positive.

FOWLER TEST

This tests the balance between the left and right ears.
This involves comparing, at the same frequency, the equality of the level of sound intensity between the two ears.
This is aimed more at predominantly unilateral deafness: the two ears must not be identical.

TONE DECAY TEST

This involves exposing the patient to a pure tone at 5 dB above the hearing threshold and observing whether it is perceived clearly for 60 seconds. Normally it would be perceived throughout this period. If not, the level is increased in 5 dB steps until it can again be heard and again successively until the patient confirms they can hear the sound for one minute.

LÜSCHER TEST

This involves distinguishing variations in the modulation of the signal.
For the ear to perceive an increase or decrease in physical intensity as a change in subjective intensity (sonority), the physical intensity must change by more than a certain value. This small change in physical intensity which the ear can perceive is called the differential threshold.

SPEECH AUDIOMETRY

Speech audiometry essentially consists of determining the threshold of intelligibility (the patient hears and understands words

pronounced) using a list of words spoken live or via recorded material.

APPLICATIONS OF AUDIOMETRY

The main applications of audiometry are:

1 Obtaining a diagnosis

To provide a diagnosis of hearing loss in a patient in one or both ears. To do this we calculate the percentage hearing loss, the (global) bilateral percentage hearing loss and the average dB hearing loss.

To evaluate distortions in the sensation of sound using suprathreshold pure tone tests.

To determine the threshold of intelligibility by means of speech audiometry or logoaudiometry.

2 To evaluate incapacity or invalidity

3 Public Health

- Epidemiological prevalence studies
- Environmental effects studies
- Occupational studies

DIAGNOSES

The SIBELMED W-50 software calculates and prints the following diagnoses:

1 «MINISTRY» DIAGNOSIS ACCORDING TO THE MINISTRY OF LABOUR AND SOCIAL AFFAIRS OSB No. 22 (January 26, 2000)
2 DIAGNOSIS OF THE COUNCIL OF PHYSICAL THERAPY
3 DIAGNOSIS OF THE MEXICAN INSTITUTE OF SOCIAL SECURITY
4 ELI (Early Loss Index)
5 SAL INDEX (Speech Average Loss)
6 KLOCKHOFF DIAGNOSIS (Modified by the Lavoro Clinic of Milan)

The parameters for each diagnosis and the calculation method of each are described in APPENDIX 2 of this manual.

4. TECHNICAL SPECIFICATIONS

SOFTWARE COMPATIBILITY AND COMPUTER REQUIREMENTS

	Minimum	Recommended
Hard Disk:	1 GB	20 GB or more
Graphic Card:	800 x 600	800 x 600 or more
Monitor:	15”	17”
Port:	RS232 / USB 2.0	

Other requirements:

Operating System: Windows 98, 2000, XP or Windows Vista.

Backup unity: Recommended

PARAMETERS

- Hearing Loss (%)
- Average Loss (dB)
- Bilateral Loss (%)
- Diagnosis (Minitry of Labour Social Affairs)
- Diagnosis (Council of Physical Therapy)
- Diagnosis (Mexican Social Security Institute)
- Diagnosis (Eli index)
- Diagnosis (Sal index)
- Diagnosis (Klockhoff index)

PERSONALISING THE PROGRAM

Software Configuration by the user at the level of:

- Type of printer
- Parameters and other
- Language
- Databases
- Communication links with the software

DATABASE

- Capability of working with different Databases
- Storage of tests
- Registration, deletion and changes to patient cards
- Quick search of the database by:
  - Record
  - Reference
  - Surname
- Printing reports from the database
- Importing / Exporting tests

STANDARDS

- Threshold pure tone audiometry in accordance with EN ISO 8253-1
- Audiogram in accordance with recommendations in EN 26189:1991 (ISO6189:1983)
- Speech audiometry in accordance with UNE-EN ISO 8253-2
  EN 62304:2006 + AC:2008
  EN 62366:2008
  EN 1041:2008
  EN 980:2008
  EN ISO 14971:2009

USEFUL LIFE

- 7 tears

5. MAINTENANCE

The **SIBELMED W-50 Audiometry Software** does not require specific maintenance, beyond what any computer program that manages data would require.

- Make a backup copy of the program in case the original becomes damaged.

- Make regular backup copies of the Databases used so they can be restored in the event of loss of information from the computer.

In the event of any problem, doubt, suggestion, etc. you may have before, during or after using the software, we recommend you follow the steps below:

1st Use the program's Help system
2nd Refer to the SIBELMED W-50 Audiometry Software's Instruction Manual
3rd Contact SIBEL S.A.'s Aftersales Service

SIBEL S.A., Rosselló 500, 08026 Barcelona
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International Sales: Tel. +34 93 436 00 07
e-mail: export@sibelmed.com
Technical serv.: Tel. +34 93 433 54 50
e-mail: sat@sibelmed.com
Fax: +34 93 436 16 11, Website: www.sibelmed.com

6. MODIFICATIONS

APPENDIX 1

COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC

COMPLIANCE WITH THE FOR DATA PROTECTION ACT. DIRECTIVE 95/46/EC

This section aims to facilitate the compliance of current legislation referring to data protection by the user with the use of this software. (Consult your local translation of the 95/46/EC directive).

A brief description of the key points of this legislation is set out and an explanation given of the action which should be taken with the **SIBELMED W-50 Audiometry Software** and/or operating system in order to comply with the requirements of the abovementioned law.

IMPORTANT WARNING

· According to current legislation, the software user, is solely responsible for the storage and treatment of their patient data in accordance with the law.

· Observance of the recommendations included in this section does, in no case, guarantee the full adaptation of user activity to the standards relating to data protection.

Requirements which specifically affect the use of the SIBELMED W-50 Audiometry Software

Identification and Authentication

The processes of identifying and authenticating users to use the **SIBELMED W-50 Audiometry Software** are carried out by the PC's operating system. For this reason only Windows Operating Systems which allow these processes to be carried out in a secure way are valid, that is, Windows NT 4, Windows 2000 , Windows XP and Windows Vista with the NTFS file system. The Windows 9x systems are not valid, neither is the FAT file system.

The PC administrator must create a unique and personalised username for each user and activate user authentication. The operating system encrypts the passwords.

Access control

The Operating System must be set up to control the access to data, i.e. permit or deny access to data. Likewise, the PC administrator must set up user account locking in order to block repeated attempts to gain unauthorised access. Consult the operating system's manual for help with setting up access controls.

Access register

Accesses to the different databases are stored on the one access register file.

Security copies (backup and recovery)

The user must, at least once a week, make back-up copies of all data in order to guarantee full recovery of data in the case of a computer system failure. In the case of the SIBELMED W-50 Audiometry Software full recoverability of all the data in all the databases can be guaranteed by saving the whole of the BDSIBEL folder which is in the application folder.

This back-up copy must be stored at all times in a different place to where the equipment on which the software is used is located.

Configuration of the Operating System

On a Windows operating system level (NT, 2000, XP and Vista) and for NTFS partitions, it is possible to restrict the access to the various databases using the file system's security features. Generally speaking, control of access to databases involves the following:

Configuration of Identification, Authentication

Each user that accesses the system must have a unique username and password, whether a local user or a network user connecting to a domain. The passwords must be changed periodically as often as desired and, while a series of passwords may remain valid, they are stored in encrypted form.

Users may be added from the Users and Passwords icon on the Control Panel. Using the Advanced Administration button on the Advanced Options tab, you can access the Local Users and Groups setup. In the Users section, new users can be created or existing properties modified. The access level of users can be set up in user properties on the Users tab of the Users and Passwords icon. We recommend that users are not given Administrator access level. In any event, the Administrator is responsible for ensuring that users use their username appropriately in accordance with technical requirements and documentation, as well as making them aware of their obligations in relation to the handling of personal data.

It is also advisable to enable the security audit feature in order to record valid and erroneous accesses on the system.

Access setup and control. File permissions

The next step is to set up the access levels, to the files which form the databases, by reference to the users which have been set up. The root of the databases is found in the folder<SIBELW50_HOME>\Bdsibel. Within it, there is a subfolder for the database, also the log file W50.log. One possible configuration is to provide full access to the <SIBELW50_HOME>\Bdsibel directory to all users (or at least to the users of the application) and to restrict access to each of the subdirectories to their respective users. In any event, the owner must always have read and write access for their subdirectory and the files that make up the subdirectory. The other users may, for example, have access to that database totally denied. Note that in this situation the users may only access their database via the application. At the level of the log

file W50.log, it would be advisable for the users to only have write access so that the application could record accesses to the various databases.

Permissions can be applied from Windows Explorer itself.Simply access the Properties of the directory or file on which you wish to establish permissions and select the Security tab. From this tab you can select both the users who may have access and the corresponding permissions (full control, read, modification, write, etc.) for each user

File audit.

We recommend the activation of the log file audit in order to record, on the security event viewer, the actions performed upon it.

To activate this option, you must first enable the audit of this file. At this level, you must specify the users (depending on the users who access the <SIBELW50_HOME>\Bdsibel directory) and types of access to be audited. The log file audit can be activated from the Security tab of the file Properties. Using the Advanced button you can access the Audit tab. From here, simply add the users and the type of access to be audited. Note that if all actions are audited via the log file, the security events viewer will have a large number of entries which will make it difficult to monitor instances of unauthorised access.

The next step is to activate the audit of access to objects, via local security configuration. To do so, access the Administrative Tools icon from the Control Panel. From there, select Local Security Policy and then Local Policies from the policies tree. You must then use Audit Object Access. Both correct and incorrect accesses can be enabled.

Finally, other files must be audited, for example the password files <SIBELW50_HOME>\Bdsibel \NAME_DB>\PW.TXT if access to the NAME_DB database by other users has not been completely restricted.

Description of the access log

Access to the various databases is recorded in one log file (W50.log) in the BDSIBEL folder of the directory where the application is installed (by default :\SIBEL\w50 and from now on <SIBELW50_HOME>\Bdsibel).

This file is created the first time that the application is launched and cannot be deactivated The system administrator is responsible for the maintenance of the size of this file, and the preparation of a monthly report where the periodic reviews carried out are analysed and any problems detected are reported.

The log file saves for each access:

- User
- Time and date of access
- Database accessed
- Action carried out on the database
- Type of access (authorised or denied)
- File path of database accessed
- Reference of the record accessed

The format for each entry is as follows:

[USER], [YYYYMMDD HH:MM:SS], [BASE], [ACTION], [ACCESS], [PATH], [REFERENCE]

The database comprises a directory and two data files (paciente.dbf and pruebas.dbf) as well as auxiliary files (indexes, etc.). The actions to be recorded are divided into:

- Action on the actual database itself (open, close, delete, etc.)

- Action on the records stored in the paciente.dbf and pruebas.dbf data files (insert, find, delete, etc.)

In any event, the log and access control file must be kept for a minimum period of two years.

Below, all actions registered on the log file are listed:

- Opening a db file
- Closing a db file
- Selecting a db
- Creating a db
- Creating a db file
- Deleting a db
- Deleting a db file
- Re-indexing a db file
- Compacting a db file
- Changing password
- Finding a record
- Adding a record
- Marking a record
- Recovering a record
- Changing a record
- Deleting a record
- Exporting a record
- Importing a record

Other important points

- Printing documents:

When paper reports containing patient data are stored, it is necessary for these documents to be stored securely such that only authorised personnel have access to them. Further, in the event that the user decides to dispose of the printed documents, it is necessary to ensure their effective physical destruction to avoid unauthorised access to the data.

- Exporting tests

The software allows tests to be exported only if the user is identified and authorised to read the database. Once a test has been exported to a file, the user of the software is responsible for the security of that file, and its subsequent deletion.

- Transmission of data:

The software supports the transmission of files containing patient data via the Internet. If this functionality is used, the user must configure their e-mail server so that the data is encrypted before transmission and is therefore converted into unreadable form to guard against any unauthorised access.

APPENDIX 2

DIAGNOSIS

1. «MINISTRY» DIAGNOSIS

The percentage of hearing loss is determined by the pure tone audiogram and according to the evaluation criteria for discapacity due to hearing deficiency as established by the Spanish Ministry of Labour and Social Affairs in OSB No. 22 of January 26, 2000.

A. Monoaural hearing loss

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 3000 Hz and added. NOTE: If one of the central frequencies is missing (1000 or 2000) and an adjacent frequency is selected, the audiometer uses this frequency to calculate the diagnosis and includes this modification in the report.

2. The corresponding hearing loss is found in Table 1.

3. If the hearing threshold is 25 dB or lower, this is not considered as loss of hearing.

Example:

Right ear (RE)	500	1000	2000	3000
dB of loss	15	10	5	10

Sum (15+10+5+10 = 40)

% Hearing loss RE 0.0 %
dB Average RE (40/4) 10.0 dB

Left ear (LE)	500	1000	2000	3000
dB of loss	35	30	40	50

Sum (35+30+40+50 = 155)

% Hearing loss RE 20.6 %
dB Average LE (155/4) 38.7 dB

B. Binaural or Bilateral hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by five and adding the loss of the worst ear and then dividing the total by six.

Binaural hearing loss in % = (5x(% loss in best ear) + (% loss in worst ear))/6.

Example:
Binaural hearing loss % = (5x0.0 + 20.6)/6 = 3.4%

C. Categories of Hearing Loss

The MINISTRY diagnosis does not establish categories of hearing loss.

However, professional clinical recommendations have led us to include the following categories depending on the hearing loss in each ear:

CATEGORIES	HEARING LOSS
. NORMAL	0 to 10%
. SLIGHT HYPOACUSIA	11 to 30%
. MODERATE HYPOACUSIA	31 to 60%
. SEVERE HYPOACUSIA	61 to 100%

Conversion of the estimated hearing level in percentage of monoaural hearing loss

TABLE FOR THE CALCULATION OF PERCENTAGE HEARING LOSS ACCORDING TO THE MINISTRY OF LABOUR AND SOCIAL AFFAIRS. OFFICIAL GAZETTE 26 JANUARY 2000.

dshl, dB	% loss	dshl, dB	% loss	dshl, dB	% loss	dshl, dB	% loss
100	0.0	170	26.2	240	52.5	310	78.8
105	1.9	175	28.1	245	54.4	315	80.6
110	3.8	180	30.0	250	56.2	320	82.5
115	5.6	185	31.9	255	58.1	325	84.4
120	7.5	190	33.8	260	60.0	330	86.2
125	9.4	195	35.6	265	61.9	335	88.1
130	11.2	200	37.5	270	63.8	340	90.0
135	13.1	205	39.4	275	65.6	345	90.9
140	15.0	210	41.2	280	67.5	350	93.8
145	16.9	215	43.1	285	69.3	355	95.6
150	18.8	220	45.0	290	71.2	360	97.5
155	20.6	225	46.9	295	73.1	365	99.4
160	22.5	230	48.9	300	75.0	370	100.0
165	24.4	235	50.5	305	76.9		

TABLE 1

2. «COUNCIL» DIAGNOSIS

The percentage of hearing loss is determined from the pure tone audiogram in accordance with the second formula of the Council of Physical Therapy.
A percentage of the hearing loss in each ear is taken at the 500, 1000, 2000 and 4000 Hz frequencies as a function of their importance, specifically 15% at 500 and 4000 Hz, 30% at 1000 Hz and 40% at 2000 Hz.
A 0% hearing loss corresponds to normal and a 100% hearing loss to cofosis. By reference to a table published by the institution, you can find the percentage hearing loss for each frequency and the level of intensity.

A. Monoaural hearing loss

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 4000 Hz and added.

2. The corresponding percentage of hearing loss for each frequency and intensity is found in Table 2.

3. The loss values for the four frequencies are added, giving the % of hearing loss of the ear under study.

Example:

Right ear (RE)	500	1000	2000	4000
dB of loss	15	10	5	10
% loss	0.5	0.3	0	0.1

Sum (0.5+0.3+0+0.1 = 0.9)

% Hearing loss RE 0.9%
dB Average RE (40/4) 10.0 dB

Left ear (LE)	500	1000	2000	4000
dB of loss	35	30	40	50
% loss	3.7	5.4	12.	9 8.0

Sum (3.7+5.4+12.9+8.0 = 30.0)

% Hearing loss LE 30.0%
dB Average LE (155/4) 38.7 dB

B. Binaural hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by seven and adding the loss of the worst ear and then dividing the total by eight.
Binaural hearing loss in % = (7x(% loss in best ear) + (% loss in worst ear))/8.

Example:
Binaural hearing loss % = (7x0.9 + 30.0)/8 = 4.5%

C. Categories of Hearing Loss

The «COUNCIL» diagnosis does not establish categories of hearing loss. However, the same categories as for the «MINISTRY» diagnosis have been adopted.

Council of Physical Therapy 2nd Formula

To arrive at the index, both ears need to be tested.

TABLE FOR THE CALCULATION OF PERCENTAGE HEARING LOSS ACCORDING TO THE COUNCIL OF PHYSICAL THERAPY.

Loss in dB	500	1000	2000	4000
5				
10	0.2	0.3	0.4	0.1
15	0.5	0.9	1.3	0.3
20	1.1	2.1	2.9	0.9
25	1.8	3.6	4.9	1.7
30	2.6	5.4	7.3	2.7
35	3.7	7.7	9.8	3.8
40	4.9	10.2	12.9	5.0
45	6.3	13.0	17.3	6.4
50	7.9	15.7	22.4	8.0
55	9.6	19.0	25.7	9.7
60	11.3	21.5	28.0	11.2
65	12.8	23.5	30.2	12.5
70	13.8	25.5	32.2	13.5
75	14.6	27.2	34.4	14.2
80	14.8	28.8	35.8	14.6
85	14.9	29.8	37.5	14.8
90	15.0	29.9	39.2	14.9
95	15.0	30.0	40.0	15.0
100				

TABLE 2

3. DIAGNOSIS OF THE MEXICAN INSTITUTE OF SOCIAL SECURITY

The percentage of hearing loss is determined from the pure tone audiogram in accordance with the Mexican Social Security Institute.

A. Monoaural hearing loss

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 3000 Hz and added.

2. The four values of each ear are added and the average is calculated.

3. The result is then multiplied by 0.8 (Fletcher Index).

Example:

Right ear (RE)	500	1000	2000	3000
dB of loss	15	10	5	10

Average = (15+10+5+10)/4 = 10 dB

% Hearing Loss RE = 10 x 0.8 = 8%
dB Average RE (40/4) 10.0 dB

Left ear (LE)	500	1000	2000	3000
dB of loss	35	30	40	50

Average = (35+30+40+50)/4 = 38.7 dB

% Hearing Loss LE = 38.7 x 0.8 = 31%
dB Average LE (155/4) 38.7 dB

B. Binaural hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by seven and adding the loss of the worst ear and then dividing the total by eight.

Binaural hearing loss in % = (7x(% loss in best ear) + (% loss in worst ear))/8.

Example:
Binaural hearing loss % = (7x8 + 31.0)/8 = 10.9 %

C. Categories of Hearing Loss

The «MEXICAN» diagnosis does not establish categories of hearing loss. However, the same categories as for the «MINISTRY» diagnosis have been adopted.

4. ELI

The ELI (Early Loss Index) is calculated from a frequency of 4000 Hz and following the tables of the Protocol for Specific Health Surveillance (Interterritorial Council of the Spanish National Health System) following the steps below:
1. The ELI is calculated by subtracting the corresponding correction value for presbycusia in Table 3 from the hearing loss at a frequency of 4000 Hz. The frequency of 4000 Hz is evaluated (considering loss due to age and gender).
2. Acoustic trauma is classified on an increasing scale of A-B-C-D-E, from lower to higher hearing capacity according to Table 4.

Example:
Patient: Male, 50 years old
Right ear (RE) 4000
dB of loss 30
Left ear (LE) 4000
dB of loss 40
Applying correction, ELI

Right ear 30 – 20 = 10 dB — Grade B Normal good
Left ear 40 – 20 = 20 dB — Grade C Normal

Table for ELI calculation
Correction for presbycusia at 4000 Hz dB
Classification of acoustic traumas

CORRECTION FOR PRESBYACUSIA AT 4,000 Hz (Db)
FOR CALCULATION OF THE ELI INDEX.

Age	Women	Men
25	0	0
30	2	3
35	3	7
40	5	11
45	8	15
50	12	20
55	15	26
60	17	32
65	18	38

TABLE 3

ELI SCALE.

Céorrected Audiometric Loss, dB	Degree of ELI	&ODVVL¿FDWLon
<8	A	Normal excellent
8-14	B	Normal good
15-22	C	Normal
23-29	D	Suspicion of deafness
>30	E	Clear indication of deafness

TABLE 4

5. SAL INDEX

The SAL Index (Speech Average Loss) evaluates the conversational frequencies (500, 1000 and 2000 Hz) and is defined as the arithmetic mean of hearing loss in decibels of these frequencies. It establishes a classification by degrees A-B-C-D-E-F-G from SAL-A (both ears are within normal limits) to SA-G (complete deafness).

Once this value has been obtained, Table 5 of the SAL Index is used to present the evaluation.

To arrive at the index, both ears need to be tested.

Clinical recommendations have led us to change the text of the SAL Index Table of the Protocol for Specific Health Surveillance (Interterritorial Council of the Spanish National Health System) according to the following:

Grade C changes from «Slightly worse» to «Slight Hearing Impairment»
Grade D changes from «Seriously worse» to «Significant Hearing Impairment»
Grade E changes from «Severely worse» to «Serious Hearing Impairment»
Grade F changes from «Extremely worse» to «Severe Hearing Impairment»
Grade F covers 91 to 99 dB and Grade G applied to 100 dB onwards.

There are some situations not covered by the evaluation table, particularly where impairment is too asymmetric, (one ear within the normal range but the other however displays serious acoustic trauma). This occurs when the best ear presents a drop of <16 dB and the worst ear presents >30 dB. In such cases, the following text is displayed:

«Detected deafness too asymmetric to be evaluated using the SAL table».

As well as the SAL Index, we obtain Monoaural hearing Loss and Binaural or Bilateral Hearing Loss, as described in the MINISTRY diagnosis.

TABLE FOR EVALUATION AND INTERPRETATION OF SAL INDEX.

Degree of Sal	dB	Class name	Characteristics
A	16 worse ear	Normal	Both ears are within normal limits, with no Gil¿Fult\ in quiet Fonversations.
B	16-30 one of the ears	Close to normal	Has Gil¿Fult\ with quiet Fonversatio- ns but nothing more.
C	31-45 better ear	Slight Auditory Loss	Has Gil¿Fulties in normal Fonversations, but not if people speak up.
D	46-60 better ear	Serious Auditory Loss	Has Gil¿Fulties even when people speak up.
E	61-90 better ear	Serious Auditory Loss	Can only hear a conversation using a hearing aid.
F	91-99 better ear	Profound Auditory Loss	Cannot hear a conversation even with a hearing aid.
G	> 100 better ear	Totally deaf in bothears	Can hear no sound at all.

TABLE 5

6. KLOCKHOOF DIAGNOSIS (Modified by the Lavoro Clinic of Milan)

For this test, the 500, 1000, 2000 and 4000 frequencies are investigated, and the criteria set out in Table 6 are applied:
1. If the threshold is not higher than 25 dB at any frequency, the diagnosis is:
«Normal»

2. If the threshold at the 4000 frequency is below 55 dB and below 25 dB in the other frequencies, the diagnosis is:
«Slight Acoustic Trauma»
«No conversational loss»

3. If the threshold at the 4000 frequency is above 55 dB and below 25 dB in the other frequencies, the diagnosis is:
«Advanced Acoustic Trauma»
«No conversational loss»

4. If there are 1 or more frequencies below 25 dB (at least one >25 dB) the diagnosis is:
«Slight hypoacusia by noise»
«Conversational loss»

5. If all the frequencies are affected but none is above 55 dB, the diagnosis is:
«Moderate hypoacusia by noise»
«Conversational loss»

6. If all the frequencies are affected and one or more are above 55 dB, the diagnosis is:
«Advanced hypoacusia by noise»
«Conversational loss»

(Diagram modified by the Lavoro Clinic of Milan)

KLOCKHOFF CLASSIFICATION.

NORMAL	The threshold does not exceed 25 dB at any frequency.		
ISOLATED ACOUSTIC TRAUMA	No conversational loss	LIGHT	The threshold at the 4000 frequency is below 55 dB and below 25 dB in the other frequencies.
		ADVANCED	The threshold at the 4000 frequency is above 55 dB and below 25 dB at the other frequencies.
GLOBAL ACOUSTIC TRAUMA	Conversational loss	LIGHT	2ne or more frequencies are not affected (are below 25 dB).
		MODERATE	All frequencies are affected (above 25 dB) but none is above 55 dB.
		ADVANCED	All frequencies are affected (above 25 dB) and one above 55 dB
OTHER LOSS not due to exposure to sound.			

TABLE 6